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ETHICAL ISSUES IN HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS IN LATIN AMERICA AND THE CARIBBEAN: DESCRIPTION OF THE PAN AMERICAN HEALTH ORGANIZATION ETHICAL REVIEW COMMITTEE DECISIONS AND PRACTICES.

Fonseca JM. Background: There is growing discussion about the protection of human subjects in biomedical research in Latin America and the Caribbean. However, only a handful of studies have been published about the knowledge, application, and acceptance within the region of international ethical guidelines and standards for human subject research. Objectives: To: 1) describe the characteristics of proposals of health research involving human participants in Latin America and the Caribbean (LAC) submitted for review to the ethical committee of the Pan American Health Organization (PAHO ERC); 2) describe the type and frequency of ethical issues identified by PAHO ERC; and 3) review the committee's approval decisions. Methods: Retrospective descriptive review of 47 proposal applications submitted to PAHO ERC from September 2001 to March 2003. Results: PAHO ERC reviewed projects from 16 (48%) of member states in LAC. Twenty-nine (62%) of projects originated in Brazil, Argentina, Mexico, and Colombia. Fourteen (30%) applications received an initial positive decision, 25 (51%) conditional, and 9 (19%) negative. PAHO ERC identified ethical issues pertaining to informed consent/recruitment information in 31 (66%) of proposals, protection and care in 19 (40%), scientific design in 16 (34%), and confidentiality in 6 (13%). The mean number of amendments requested by PAHO ERC was 0.2 for proposal granted positive initial decisions, 3.6 for conditional, and 8.1 for negative. Forty (98%) of all finalized evaluations receive a final positive decision. Proposals subject to US or Canadian ethical rules or regulations were associated with higher approval rate on initial review and with a lower number of amendments. The author found no association between initial approval decision and proposal budget, number of investigators, type of PAHO research grant program, or level of scientific output in the country in which the study is held. Neither was an association found between these factors and the number of protocol amendments required by the committee. Conclusions: The ethics of research involving human participants remains an issue in Latin America, particularly the emphasis given to international ethical standards by investigators in their proposals and by ethical committees in their reviews. The knowledge, application and acceptance of existing standards within the region require further study.

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